

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

P082

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on 2-3-06Signature Abby BergheilaTyped or printed name ABBY BERGHELLA

Application Number

10/180,553

Filed

2-18-04

First Named Inventor

RICHARD SCHATZ ET AL.

Art Unit

1614

Examiner

COOK, REBECCA

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record.
Registration number 38,699☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____Cindy A. Lynch
SignatureCINDY A. LYNCH
Typed or printed name(650) 614-4131
Telephone number2-3-06
DateNOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Dated: 2-3-06

Signature: Abby Berghella (Abby Berghella)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Richard Schatz *et al.*

Application No.: **10/780,553**

Filing Date: 18 February 2004

For: Method for Preventing Restenosis using a
Substituted Adenine Derivative

Art Unit: 1614

Examiner: Cook, Rebecca

Attorney Ref. No.: P082

PRE-APPEAL REQUEST FOR REVIEW

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action dated 3 November 2005, the response period extending through 3 February 2006, Applicant requests a Pre-Appeal Brief Review in accordance with the guidelines set forth in the 12 July 2005 Official Gazette Notice (New Pre-Appeal Brief Conference Pilot Program, 1296 *Off. Gaz. Pat. Office* 67 (July 12, 2005); *see also* Extension of the Pilot Pre-Appeal Brief Conference Program, _____ *Off. Gaz. Pat. Office* _____ (January 10, 2006)) (collectively, "Notice"). Reconsideration of this application by a three Examiner panel is requested in view of the following remarks which identify the errors in facts, and the omission of essential elements required to establish a *prima facie* rejection.

Summary of Final Office Action and Status of Application

The Office Action again rejects Claims 16 and 18 under 35 U.S.C. § 112, first paragraph, for allegedly failing to be supported by an adequate written description of the claimed invention. The subject matter of Claim 17, dependent from Claim 16, has been indicated to be allowable.

Summary of the Claimed Invention

As requested in the Notice, a summary of the claimed invention can be found in Applicant's Response filed 6 September 2005 ("Response"), in the full paragraphs appearing at page 5 thereof.

Omission of Essential Elements Required for a *prima facie* case Necessitating Review

In the Response filed 6 September 2005, Applicant detailed the legal background of the 'Written Description' requirement of section 112, first paragraph, and therefore the factual showing that must be made in an Office Action when a rejection is made alleging that a claim fails to satisfy that mandate. Response, pages 3-4. Among those requirements is the evaluation in the Office Action of "whether one of skill in the art would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed or claimed" and, therefore, also an evaluation of the level of skill in the art of the hypothetical person of ordinary skill in the art. As also specifically pointed out in the Response (see, e.g., page 4), the U.S. Patent and Trademark Office bears the burden of presenting evidence and reasoning why claimed subject matter allegedly does not satisfy the Written Description requirement.

Instead of presenting the evidence and reasoning required (see, e.g., M.P.E.P. § 2163) to establish a *prima facie* case, the Office Action only states:

There is no implication in the specification that the instant method is intended to include carriers such as [examples cited by Applicant in the Response].

The first Office Action was equally deficient, stating only:

However, the specification does not disclose any carrier other than a stent (column 3, lines 20-21). One skilled in the art would not know what other carriers other than a stent would be included in the recitation “with a carrier.”

(May 4, 2005, Office Action, page 2)

Both Office Actions clearly applied incorrect standards for assessing whether or not the claims and accompanying specification meet the Written Description requirement, and therefore plainly fail to include all of the essential elements for making a rejection under 35 U.S.C. § 112, first paragraph.

Fundamentally, the Office Action must include evidence and reasoning why the ordinarily skilled artisan, upon a full and fair reading of the specification, would not conclude that the inventors had possession of the invention claimed in Claims 16 and 18, and more specifically why the inventors allegedly did not have possession of the genus “carrier”. In stark contrast to this bare minimum, the first Office Action questioned whether or not the skilled artisan herself would appreciate all ‘carriers’ other than a stent, while the final Office Action queries what was the Applicant’s ‘intended’ meaning when reciting both a “carrier” and a “stent” in the specification and claims. Both Office Actions applied incorrect standards for assessing the Written Description requirement of section 112, first paragraph, and are therefore fatally flawed.

Particularly notable, for its absence, is the Office Action failing to directly face the fact that the specification specifically recites that a “carrier” can be used (col. 3, lines 17-20), and that a representative species of that carrier can be a “stent” (col. 3, lines 20-21). Applicant has already explained (Response, pages 5 and 6) why this disclosure more than adequately satisfies the Written Description requirement; in response, the Office Action is silent. Instead the Office Action merely concludes that the Written Description requirement hasn’t been met, without offering any facts or reasoning in support of that otherwise bald assertion.

Accordingly, the Office Action fails to include essential elements to establish a *prima facie* case, because it lacks at least:

- an application of the correct legal standard;
- an allegation of any fact in support of the rejection;
- any reasoning in support of the rejection; and
- an evaluation of why the Applicant cannot claim a “carrier” when the specification specifically recites a “carrier”.

For at least the foregoing reasons, Applicant respectfully submits that the Office Action fails to include essential elements for establishing a *prima facie* case in support of the rejection of Claims 16 and 18 under 35 U.S.C. § 112, first paragraph.

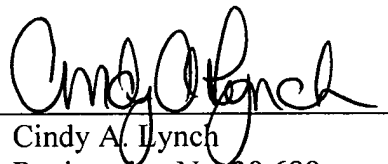
Conclusion

Applicant respectfully submits that this application is in immediate and clear form for allowance based on the clear errors and omissions cited above. Accordingly, an early indication, via Notices of Allowance and Allowability, that all claims are allowed, is respectfully requested. Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining

issues pertaining to this application, the undersigned respectfully requests that she be contacted at the number indicated below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to Deposit Account 50-3100.

Respectfully submitted,

By: 
Cindy A. Lynch
Registration No. 38,699

U.S. P.T.O. Customer Number 43027

Conor Medsystems, Inc.
1003 Hamilton Court
Menlo Park, CA 94025

650.614.4131 (v)

Date: February 3, 2006